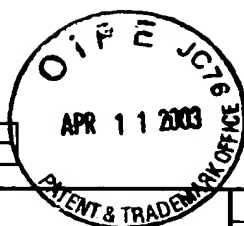


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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 8

### Complete if Known

|                        |                    |
|------------------------|--------------------|
| Application Number     | 09/667,328         |
| Filing Date            | September 21, 2000 |
| First Named Inventor   | PACE et al.        |
| Group Art Unit         | 1616               |
| Examiner Name          | S. Gollamudi       |
| Attorney Docket Number | 401909/SKYE PHARMA |

### U.S. PATENT DOCUMENTS

| Examiner<br>Initials | Doc. No. | U.S. Patent Document            |              | Name of Patentee or Applicant | Date of<br>Publication | Filing Date if<br>Appropriate |
|----------------------|----------|---------------------------------|--------------|-------------------------------|------------------------|-------------------------------|
|                      |          | Application or<br>Patent Number | Kind<br>Code |                               |                        |                               |
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Sheet 2 of 8

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| YJ                   | 77       | 4826687                         |              | Nerome et al.                 | 5/2/1989               |                               |

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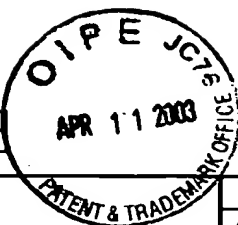
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Sheet 3 of 8

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| Application Number     | 09/667,328         |
| Filing Date            | September 21, 2000 |
| First Named Inventor   | PACE et al.        |
| Group Art Unit         | 1616               |
| Examiner Name          | S. Gollamudi       |
| Attorney Docket Number | 401909/SKYEPhARMA  |

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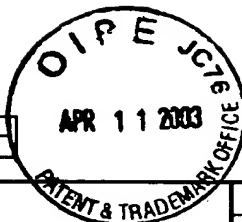
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Sheet 4 of 8

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|                        |                    |
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| Application Number     | 09/667,328         |
| Filing Date            | September 21, 2000 |
| First Named Inventor   | PACE et al.        |
| Group Art Unit         | 1616               |
| Examiner Name          | S. Gollamudi       |
| Attorney Docket Number | 401909/SKYE PHARMA |

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|                      |          | Application or<br>Patent Number | Kind<br>Code |                               |                        |                               |
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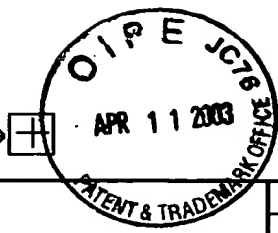
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Group Art Unit 1616  
Examiner Name S. Gollamudi  
Attorney Docket Number 401909/SKYE PHARMA

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|-------------------|----------|-------------------------|------------------------------|-----------|---|---------------------|-------------|----------------|
|                   |          | Office                  | Application or Patent Number | Kind Code |   |                     | Yes         | No**           |
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|                   | 162      | EP                      | 0 602 700                    |           | Pharmacia AB  | 12/20/1995          |             |                |
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|                   | 164      | EP                      | 0 724 877                    |           | CL Pharma. (see Doc. No. 128)   | 2/12/1997           |             | X <sup>+</sup> |
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|                   | 171      | JP                      | 60208910                     |           |   |                     |             |                |

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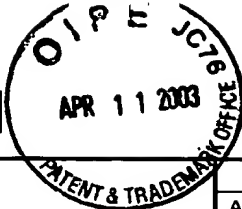
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\* Note References that do not have an English abstract or translation have not been considered.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 8

### Complete if Known

|                        |                    |
|------------------------|--------------------|
| Application Number     | 09/667,328         |
| Filing Date            | September 21, 2000 |
| First Named Inventor   | PACE et al.        |
| Group Art Unit         | 1616               |
| Examiner Name          | S. Gollamudi       |
| Attorney Docket Number | 401909/SKYE PHARMA |

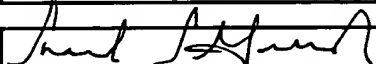
### FOREIGN PATENT DOCUMENTS

| Examiner<br>Initials | Doc. No. | Foreign Patent Document |                                 |              | Name of Patentee or Applicant                | Date of<br>Publication | Translation |      |
|----------------------|----------|-------------------------|---------------------------------|--------------|--|------------------------|-------------|------|
|                      |          | Office                  | Application or<br>Patent Number | Kind<br>Code |  |                        | Yes         | No** |
|                      | 172      | JP                      | 83233915                        |              | Green Cross Corp. (see Doc. No. 97)          | 10/21/1985             |             | X*   |
|                      | 173      | JP                      | 63502117                        |              | Liposome Technology, Inc. (see Doc. No. 175) | 8/13/1987              |             | X*   |
|                      | 174      | WO                      | 85/00011                        |              | University of Miami                          | 1/3/1985               |             |      |
|                      | 175      | WO                      | 87/04592                        |              | Liposome Technology, Inc.                    | 8/13/1987              |             |      |
|                      | 176      | WO                      | 88/04924                        |              | Liposome Technology, inc.                    | 7/14/1988              |             |      |
|                      | 177      | WO                      | 91/04011                        |              | Riker Laboratories, Inc.                     | 4/4/1991               |             |      |
|                      | 178      | WO                      | 00/30616                        |              | RTP Pharma Inc.                              | 6/2/2000               |             |      |
|                      | 179      | WO                      | 01/30372                        |              | Basf Aktiengesellschaft                      | 5/3/2001               |             | X*   |
|                      | 180      | WO                      | 92/18105                        |              | Sandoz Ltd.                                  | 10/29/1992             |             |      |
|                      | 181      | WO                      | 94/20072                        |              | Pharmacia AB                                 | 9/15/1994              |             |      |
|                      | 182      | WO                      | 96/21439                        |              | Galephar P.R. Inc.                           | 7/18/1996              |             |      |
|                      | 183      | WO                      | 96/24332                        |              | Nanosystems L.L.C.                           | 8/15/1996              |             |      |
|                      | 184      | WO                      | 97/14407                        |              | Research Triangle<br>Pharmaceuticals         | 4/24/1997              |             |      |
|                      | 185      | WO                      | 98/07414                        |              | Research Triangle<br>Pharmaceuticals Ltd.    | 2/26/1998              |             |      |
|                      | 186      | WO                      | 98/41239                        |              | Nycomed Imaging AS                           | 9/24/1998              |             |      |
|                      | 187      | WO                      | 99/49846                        |              | RTP Pharma Inc.                              | 10/7/1999              |             |      |
|                      | 188      | WO                      | 99/61001                        |              | RTP Pharma Inc.                              | 12/2/1999              |             |      |

### OTHER - NON PATENT LITERATURE DOCUMENTS

| Examiner<br>Initials | Doc. No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published. | Translation |      |
|----------------------|----------|--|-------------|------|
|                      |          |  | Yes         | No** |
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|                      | 192      | MISHRA et al., "Scientifically Speaking: Novel Injectable Formulations of Water-Insoluble Drugs", <i>Controlled Release Newsletter</i> , Vol. 17, Issue 2, Jun 2000, pp. 21-30   |             |      |
|                      | 193      | BANGHAM et al., "Diffusion of Univalent Ions Across the Lamellae of Swollen Phospholipids", <i>J. Mol. Biol.</i> , 1965, Vol. 13, pp. 238-252  |             |      |
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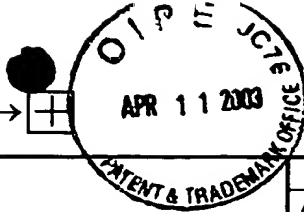
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| Examiner Name          | S. Gollamudi       |
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|----------------------|----------|--|-------------|------|
|                      |          |  | Yes         | No** |
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| <i>KA</i>            | 212      | PACE et al., "Novel Injectable Formulations of Insoluble Drugs", <i>Pharmaceutical Technology</i> , Vol. 23, No. 3, Mar 1999, pp. 116-134  |             |      |
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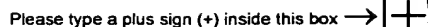
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